The specification is amended to conform to suggested application format. Claim 6 is amended, and new claims 12-20 are added. Support for the new claims is found at page 4, second and third paragraphs, and page 7, first full paragraph. Claims 1-20 are now pending.

There are four rejections under 35 USC 103 presented in the Office Action. Applicants traverse each of these rejections.

First, claims 1 – 5 and 7 – 11 are rejected over Faour et al. (6,491,949), alone. This rejection is traversed on the basis that the dosage form of the present invention is fundamentally different from the disclosed device of Faour.

As set forth in claims 1 and 7, a semipermeable layer surrounds both the core and first layer portions, which both contain the same pharmaceutically active agent. The dosage form of the present invention allows for a release profile other than a zero order release, i.e. a release order approaching or reaching a first order release. An advantage of such a profile is a faster, earlier rate of drug release, providing quicker therapeutic relief.

On the other hand, Faour discloses a dual osmotic device, wherein a core is surrounded by a first semipermeable layer, which is surrounded by another layer of drug and another semipermeable layer surrounding this second drug layer, i.e. an osmotic device within an osmotic device. The core and outer drug layer have at least one passageway for release of the drug. There is a lag phase before the release of the active agent from the core (i.e., 3 hours – see col. 1, lines 59-62) at which time the release profile is zero order;

the outer layer can be made to release drug more quickly or more slowly than the core, although there is still a lag phase of 20 minutes.

One skilled in the art would not have been motivated or instructed by the Faour patent to develop the osmotic system of the present invention. Although both are osmotic dosage forms, the concepts and purpose are entirely different and result in different release profiles. Accordingly, it is respectfully submitted that the Faour patent does not render any of the claims obvious under §103. Withdrawal, therefore, is earnestly solicited.

Second, claim 6 is rejected as obvious over Faour in view of Hamel (4,801,461).

Claim 6 includes the requirements of independent claim 1, which for the reasons stated above is not obvious in view of Faour. The additional teaching of a dosage form with pseodoephedrine does not make up for the deficiencies of the primary reference. Therefore, reconsideration and withdrawal are deemed proper.

Third, claims 1 – 3 and 7 are rejected under 25 USC 103 over Savastano (5,681,584) in view of Fassihi (5, 783,212). This rejection is also traversed.

Savastano discloses an osmotic type of device containing a core of the active substance surrounded by a "delay" layer, further surrounded by a semipermeable membrane. The device may have a drug-containing overcoat on the outside. The idea is to provide for a delayed release of a substantial amount of the core active until the dosage form reaches the colon, and this is

accomplished by the use of the delay jacket. Essentially, the osmotic device prolongs the usual lag phase of drug release by this type of dosage form by several hours, at which time zero order kinetic release is observed.

On the other hand, the osmotic system as claimed herein is constructed so that the lag phase is shortened, to an extent that a first order kinetic profile is approached or reached. This is not taught or suggested by Savastano.

Fassihi discloses a drug delivery system, the purpose of which is to obtain zero order release of drug. The tablet described has two barrier layers and a drug layer, whereby as the barrier layers swell and dissolve, the pharmaceutical agent from the drug layer diffuses out. In the passage cited by the Examiner, it is disclosed that when a high concentration of the active agent or of a second active agent is desired, it can be included in one or both of the barrier layers. It does not state or suggest that the barrier layer contain a higher concentration of active agent then the drug layer. Rather it is addressing the concentration (actually, level) of drug released.

Thus, the references, alone or in combination, do not teach an osmotic system comprising a core portion of one concentration and a layer portion of a higher concentration, both surrounded by a semipermeable membrane, the purpose of which is to obtain release profiles more on the first order scale than zero order. Accordingly, a *prima facie* case of obviousness has not been established, and this rejection should be withdrawn.

Finally, all of the claims are rejected as being allegedly obvious over Savastano in view of Faour (6,004,582). This rejection is also traversed.

The rejection alleges that Savastano teaches all aspects of the present invention, except the concentration of actives in the respective layers. For this, Faour is cited for teaching manipulation of drug concentrations in different layers.

As mentioned previously in this Response, the dosage form of Savastano is very different from the one of the present invention. The combination with Faour does not lead to the osmotic system Applicants claim in independent claims 1 and 7 (and thus not to the dependent claims). Neither reference discloses or suggests a dosage form containing a core portion and a layer portion, both of which are surrounded by a semipermeable coat. Therefore, reconsideration and withdraw are proper and are earnestly solicited.

Applicants respectfully submit that the new dependent claims are not obvious over the cited references on the basis of the remarks made herein.

In view of the amendments and remarks above, Applicants respectfully submit that this application is in condition for allowance. If there are any matters remaining that could best be resolved by a telephone or personal interview, the Examiner is invited to contact the undersigned at the number listed below.

This Response is being filed before the three-month expiration date.

Therefore, no fees are due with this paper.

Respectfully submitted,

Mary E. Gormley

SHIRE LABORATORIES INC.
1550 East Gude Drive
Rockville, MD 20850
Tel: 301/838-2658
Fax: 301/838-2501
Email: mgormley@shirelabs.com

Mary E. Gormley
Registration No. 34,409
Attorney for Applicant(s)

APPENDIX TO AMENDMENT OF December 31, 2002
Version with Markings to Show Changes Made

Amendments to the Specification

Please make the following amendment(s) to the specification:

On page 1 of the specification, below the Title and above the first paragraph, insert:

--Field of the Invention--

Between the first and second paragraphs on page 1 of the specification, insert

--Background of the Invention--

On page 2 of the specification, above the first full paragraph, insert

--Summary of the Invention--

On page 2 of the specification, between the first and second paragraphs, insert:

--Brief Description of the Drawings

Figure 1 is a depiction of a tablet according to the present invention.

Detailed Description of the Invention--

Amendments to the Claims

Please make the following amendment(s) to the claims:

Please amend claim 6 as follows:

6. The system of claim 1 wherein said pharmaceutically active agent is pseudoephedrine or its salts.

Please add claims 12-20.